

Attorney Docket No.: 00.22US

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Maes, et al.

Serial No.: 09/773,351

Group Art Unit: 1619

Filed: January 31, 2001

Examiner: Willis, M.

For: Cholesterol Sulfate and Amino Sugar Compositions for Enhancement of Stratum Comeum Function

#14
AKO
8-14-02**RESPONSE PURSUANT TO 37 CFR 1.111**

The Assistant Commissioner of Patents and Trademarks

Washington, D.C. 20231

Dear Sir:

In response to the Examiner's Final Action dated May 1, 2002, please consider the following remarks which are believed to place the application in condition for allowance or in better condition for appeal in the event the final rejection is maintained.

REMARKS

The Examiner maintains a rejection of claim 19 under section 112, first paragraph for failing to describe subject matter such that one of ordinary skill in the art would be enabled to make and/or use the present invention. Applicants have previously argued that the term "preventing" as used in claim 19 in connection with the description provided in the present specification, as well as in light of the explanation of the mechanism of the skin barrier function provided in Applicants' Responses of March 12, 2002 and of April 12, 2002, demonstrates that this term is sufficient to enable one of ordinary skill in the art to make and/or use the present invention. In response, the Examiner finds that there is no data in the specification to allow a prediction of certain types of damage to the skin. However, it is not necessary for a specification to disclose what is already known in the art. Further, Applicants did not qualify the degree of accuracy with which a prediction is made, as this is not necessary. Anyone knows that damage is caused to the skin by the sun or by natural aging. Applicants merely provided this information, both in the specification as well as in the responses, to support the fact that preventing damage to the skin is predictably associated with a reduction or loss of the skin barrier function.

Applicants provide the only data necessary to enable the present invention. In Example 1, at pages 8 to 10, the present specification demonstrates an 88 percent barrier repair over a placebo. The barrier repair was measured by the recovery of the skin on the stripped and treated side of the face in comparison with the

stripped and untreated side of the face. The Examiner also notes that broad correlations may exist between the loss or reduction of skin barrier function, and various trends in the pathology of the skin. However, the Examiner goes on to say, that the prediction of the exact amount of skin pathology is beyond the current state of the art. Applicants do not aim to make any predictions about the skin pathology of any particular individual. The claims of the present invention to meet the enablement requirement do not require such a prediction. Rather what is required is that the term "preventing" as used in Claim 19 read in view of the present specification be sufficient to enable one of ordinary skill in the art to make and/or use the present invention. Applying this standard, Applicants have demonstrated that one of ordinary skill in the art would be enabled to make and/or use the present invention.

The Examiner finds that it incorrect that to reduce a condition that exists inherently prevents that condition. However, it is not incorrect, as the Examiner believes, because the reduction of the condition is not the separate situation of a vaccination example presented by the Examiner. When a symptom exists and it is reduced by treatment, it is this very same treatment that keeps the condition from occurring further. This is the very same definition that was taken from the dictionary in Applicants Response of April 12, 2002, and therefore, Applicants' argument is fully supported by what is known to one of ordinary skill in the art. Thus, the present specification fully enables one of ordinary skill in the art to prevent damage to the skin as described in claim 19, and Applicants respectfully request that the Examiner's rejections based on lack of enablement under 35 U.S.C. §112, first paragraph be withdrawn.

The Examiner maintains in the final office that Ribier et al. (U.S. Patent No. 5,650,166; "the '166 reference") in view of Subbiah (U.S. Patent No. 6,150,381; "the '381 reference") renders claims 1 to 20 of the present invention obvious under 35 U.S.C. §103(a) because a mixture includes random solutions and ordered compositions. However, there is no support provided to indicate why or how one of ordinary skill in the art would understand that a mixture of the present invention is taught or suggested by a lipid vesicle described in the '166 reference. There is no teaching, suggestion or motivation in the art or the knowledge of one of ordinary skill in the art to support the assertion that mixing components is equivalent to or includes encapsulating components. Any instruction to mix ingredients is not understood by one of ordinary skill in the art to arrange the ingredients in an orderly fashion. This is contrary to the logic of anyone, let alone one of ordinary skill in the art. As previously discussed in the Response of April 12, 2002, specific processing steps to make a lipid vesicle of a certain order are taught and/or suggested at column 7, line 42 of the '166 reference, "A) Production of lipid vesicles containing ASL" to column 8, line 4 "B) Production of the cosmetic composition." If a mixture was a lipid vesicle, the authors of the '166 reference would not have to go into such detail with respect to the processing steps. All they would have needed to do is state "mix the ingredients." A mixture of the ingredients that it takes to make a lipid vesicle certainly does not make a lipid

vesicle. A mixture of cholesterol sulphate and an exfoliant as is the subject of the present invention is not taught or suggested by the combination of the '381 reference and the '166 reference fails to teach or suggest the present invention, and a *prima facie* case of obviousness has not been made.

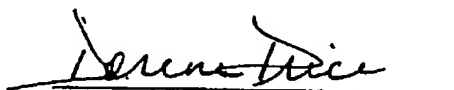
Finally, even if, a *prima facie* case could be made, it would be rebutted by the surprising results of the present invention. As noted in the present specification at page 4, lines 1 to 12, it is unexpected to find that two opposing components would not cancel each other out when combined as a mixture in a composition. The exfoliating components have an activity that is opposite that of the cholesterol sulfate which thickens and strengthens the protective barrier of the skin. When combined as a mixture in the compositions of the present invention, barrier repair is achieved. This is a surprising and unexpected result that is not taught or suggested by the cited references. Because none of the cited references alone nor in combination would lead one of ordinary skill in the art to the compositions and methods of the present invention, a *prima facie* case of obviousness has not been established. Applicants request therefore, that the Examiner's rejection under §103 be withdrawn.

CONCLUSION

In view of the arguments presented above in the present submission, the claims are believed to be in condition for allowance, and issuance of a Notice of Allowance is respectfully solicited.

Respectfully submitted,

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